

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

BAYER SCHERING PHARMA AG and  
BAYER HEALTHCARE  
PHARMACEUTICALS, INC.,

Plaintiffs,

-against-

SANDOZ, INC., WATSON  
PHARMACEUTICALS, INC., and  
WATSON LABORATORIES,

Defendants.

Civil Action No. 2:08 CV 3710 PAC

**ANSWER, AFFIRMATIVE  
DEFENSES, AND  
COUNTERCLAIMS**

SANDOZ, INC.,

Counterclaimant,

-against-

BAYER SCHERING PHARMA AG and  
BAYER HEALTHCARE  
PHARMACEUTICALS, INC.

Counterclaim defendants.

Defendant, SANDOZ, INC. (“Sandoz”), through its undersigned counsel, Kelley Drye & Warren LLP, for its Answer to the Complaint filed by BAYER SCHERING PHARMA AG (“Bayer Schering”) and BAYER HEALTHCARE PHARMACEUTICALS, INC. (“Bayer Healthcare,” and, collectively with Bayer Schering, “Bayer” or “Plaintiffs”), hereby responds as follows:

**RESPONSE TO ALLEGATIONS**

1. Admits in respect of Paragraph 1 of the Complaint that Plaintiffs have instituted an action for patent infringement and that this Court has jurisdiction over such an action under 28 U.S.C. §§ 1331 and 1338(a), but denies that the action has any merit or validity whatsoever, and except as so admitted, denies each and every other allegation contained therein.

2. Admits the allegations of Paragraph 2 of the Complaint.

3. Admits the allegations of Paragraph 3 of the Complaint.

4. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 4 of the Complaint, and, therefore, denies the same.

5. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 5 of the Complaint, and, therefore, denies the same.

6. Admits the allegations of Paragraph 6 of the Complaint.

7. Admits, in respect of Paragraph 7 of the Complaint, that Sandoz transacts business in the State of New York, that Sandoz operates a manufacturing facility in the State of New York, that Sandoz derives substantial revenue from interstate and international commerce, including revenue from the State of New York and the Southern District of New York, that Sandoz is registered with the New York Department of State Division of Corporations as a foreign corporation, and that Sandoz has filed an ANDA, but denies that any such conduct constitutes a tortious act, and except as so admitted and denied, denies each and every other allegation contained therein.

8. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 8 of the Complaint, and, therefore, denies the same.

9. Lacks knowledge or information sufficient to form a belief as to the truth of admit or deny the allegations of Paragraph 9 of the Complaint, and, therefore, denies the same.

10. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 10 of the Complaint, and, therefore, denies the same.

11. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 11 of the Complaint, and, therefore, denies the same.

12. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 12 of the Complaint, and, therefore, denies the same.

13. Admits the allegations of Paragraph 13 of the Complaint.

14. Admits the allegations of Paragraph 14 of the Complaint.

15. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 15 of the Complaint, and, therefore, denies the same.

16. Admits the allegations of Paragraph 16 of the Complaint.

17. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 17 of the Complaint, and, therefore, denies the same.

18. Admits the allegations of Paragraph 18 of the Complaint.

19. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 19 of the Complaint, and, therefore, denies the same.

20. Admits in respect of Paragraph 20 of the Complaint that a photocopy of United States Patent No. 5,569,652 is attached to the Complaint as Exhibit 1 and sets forth certain information set on its face, but lacks knowledge or information, except as so admitted and denied, denies each and every other allegation contained therein.

21. Admits with respect to Paragraph 21 of the Complaint that U.S. Patent No. 5,569,652 has been listed in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (“the Orange Book”) but denies that the ‘652 patent covers any FDA approved use of Bayer Healthcare’s Yasmin<sup>®</sup> product, and except as so admitted and denied, denies each and every other allegation contained therein, lacking knowledge or information sufficient to form a belief as to the truth of such other allegations.

22. In respect of Paragraph 22 of the Complaint, defendant Sandoz incorporates by reference its responses to Paragraphs 1 through 21 of the Complaint.

23. Denies the allegations of Paragraph 23 of the Complaint.

24. Denies the allegations of Paragraph 24 of the Complaint.

25. Admits with respect to Paragraph 25 that by filing its ANDA Sandoz has indicated its ANDA product will be bioequivalent to Yasmin<sup>®</sup> product with respect to FDA approved uses, but denies each and every other allegation contained therein.

26. In respect of Paragraph 26 of the complaint, Sandoz denies that Sandoz will be marketing its ANDA product with specific intent, and/or with the desire to actively induce, aid, abet infringement of the '652 patent, or that it knows or reasonably should know that its proposed conduct will induce infringement, and with respect to the other allegations in such paragraph, response requires either a legal conclusion of law or defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore, denies the same, and respectfully refers any legal conclusions for the courts decision.

27. With respect to Paragraph 27, lacks knowledge or information sufficient to form a belief as to what the FDA will or will not require its label to provide with respect to information for patients regarding anti-aldosterone and anti-androgenic properties of drospirenone (= dihydrospirorenone), and denies each and every other allegation contained therein.

28. Denies the allegations of Paragraph 28 of the Complaint.

29. Admits that allegations of Paragraph 29 of the Complaint.

30. With respect to Paragraph 30, admits that it makes representations to its customers, when appropriate, that its products are bioequivalent to a corresponding brand name product, but denies that such implies that its products are suitable for any pharmacological use that the corresponding branded product may be employed for in the medical community, and except as so admitted and denied, denies each and every other allegation contained therein.

31. Denies the allegations of Paragraph 31 of the Complaint.

32. Denies the allegations of Paragraph 32 of the Complaint.

33. In respect of Paragraph 33 of the Complaint, defendant Sandoz incorporates by reference its responses to Paragraphs 1 through 32 of the Complaint.

34. Denies the allegations of Paragraph 34 of the Complaint.

35. Denies the allegations of Paragraph 35 of the Complaint.

36. States that no response is required to the allegations of Paragraph 36 of the Complaint as it does not pertain to Sandoz.

37. States that no response is required to the allegations of Paragraph 37 of the Complaint as it does not pertain to Sandoz.

38. States that no response is required to the allegations of Paragraph 38 of the Complaint as it does not pertain to Sandoz.

39. States that no response is required to the allegations of Paragraph 39 of the Complaint as it does not pertain to Sandoz.

40. States that no response is required to the allegations of Paragraph 40 of the Complaint as it does not pertain to Sandoz.

41. States that no response is required to the allegations of Paragraph 41 of the Complaint as it does not pertain to Sandoz.

42. States that no response is required to the allegations of Paragraph 42 of the Complaint as it does not pertain to Sandoz.

43. States that no response is required to the allegations of Paragraph 43 of the Complaint as it does not pertain to Sandoz.

44. States that no response is required to the allegations of Paragraph 44 of the Complaint as it does not pertain to Sandoz.

45. States that no response is required to the allegations of Paragraph 45 of the Complaint as it does not pertain to Sandoz.

46. States that no response is required to the allegations of Paragraph 46 of the Complaint as it does not pertain to Sandoz.

47. States that no response is required to the allegations of Paragraph 47 of the Complaint as it does not pertain to Sandoz.

48. States that no response is required to the allegations of Paragraph 48 of the Complaint as it does not pertain to Sandoz.

49. States that no response is required to the allegations of Paragraph 49 of the Complaint as it does not pertain to Sandoz

50. Denies that Plaintiffs are entitled to any relief as set forth in A – E of Plaintiffs’ “Prayer for Relief.”

**AFFIRMATIVE DEFENSES**

Sandoz sets forth the following affirmative and other defenses. Sandoz does not intend hereby to assume the burden of proof with respect to those matters that, pursuant to law, Plaintiffs bear the burden.

**First Affirmative Defense**

51. The claims alleged in the Complaint are barred by the applicable statute of limitations.

**Second Affirmative Defense**

52. The claims alleged in the Complaint are barred by the equitable doctrines of laches, waiver and estoppel.

**Third Affirmative Defense**

53. The claims alleged in the Complaint are barred in whole or in part by the doctrine of unclean hands.

**Fourth Affirmative Defense**

54. Plaintiffs are not entitled to any relief because it has not suffered any harm or incurred any damages as a result of any actions of Sandoz.

**Sixth Affirmative Defense**

55. Defendant Sandoz has not, does not, and will not, willfully or otherwise infringe any valid and enforceable claim of U.S. Patent No 5,569,652.

**Seventh Affirmative Defense**

56. Defendant Sandoz has not, does not, and will not, induce or contribute to any infringement of any valid and enforceable claim of U.S. Patent No 5,569,652.

**Eighth Affirmative Defense**

57. Each of the claims of U.S. Patent No. 5,569,652 are invalid for failure to satisfy the provisions of one or more of sections of U.S.C. §§101 *et seq.*, including without limitation, §§102, 103, 112, and 282, and/or for double patenting.

**Ninth Affirmative Defense**

58. Plaintiffs are estopped from asserting defendant's accused products infringe any of the claims of U.S. Patent No. 5,569,652 by reasons of actions taken and statements made in the United States Patent and Trademark Office during the prosecution of the application which led to U.S. Patent No. 5,569,652.

**Tenth Affirmative Defense**

59. U.S. Patent No. 5,569,652 is unenforceable as a result of inequitable conduct of Plaintiffs and their representatives who were aware of information material to the patentability of U.S. Patent No. 5,569,652, but withheld concealed, and/or mischaracterized the information with an intent to deceive the United States Patent and Trademark Office, as set forth in the third counterclaim set forth below.

**Eleventh Affirmative Defense**

60. The complaint fails to state a claim for which the relief sought may be granted.

## **COUNTERCLAIMS**

Sandoz brings the following Counterclaims against Plaintiffs for declaratory judgment that U.S. Patent Nos. 5,569,652 (“the ‘652 patent”), 6,787,531 (“the ‘531 patent”), 6,933,395 (“the ‘395 patent”) are not infringed and that each of the claims of such patents are invalid, and that the claims of U.S. Patent No. 5,569,652 are unenforceable for inequitable conduct. Furthermore, these Counterclaims are also directed to violations of the antitrust laws of the United States.

### **The Parties**

1. Defendant-counterclaimant Sandoz (“Sandoz”) is a Colorado corporation with an office at 506 Carnegie Center, Suite 400, Princeton NJ 08540.

2. Upon information and belief, Counterclaim-defendant Bayer Schering is a corporation organized and existing under the laws of Germany with a principal place of business at Mullerstrasse 178, 13353 Berlin Germany.

3. Upon information and belief, Counterclaim-defendant Bayer Healthcare is a Delaware corporation with a principal place of business at 340 Changebridge Road, PO Box 1000, Montville, NJ 07045-1000. (Bayer Schering and Bayer Healthcare are collectively referred to as “Bayer” or Counterclaim-defendants”).

### **Jurisdiction and Venue**

4. This Court has jurisdiction over these Counterclaims under 28 U.S.C. § 1331, 28 U.S.C. § 1338, and 28 U.S.C. § 2201. The Counterclaims are for a declaratory judgment for non-infringement and invalidity arising under the patent laws of the United States

35 U.S.C. § 101 et. seq.; and for intentional acts of monopolization, attempted monopolization and restraint of trade in violation of the Sherman Act, 15 U.S.C. § 1 et. seq.

5. Venue is proper in this Court under 28 U.S.C. § 1391(b) because this is a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred.

6. Bayer submitted to the jurisdiction of this Court by filing the Complaint in this action.

#### **First Counterclaim**

#### **DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF U.S. PATENT 5,569,652**

7. Sandoz repeats and realleges the allegations contained in paragraphs 1 through 6, inclusive, of these Counterclaims as if fully set forth herein.

8. Sandoz does not infringe, contribute to the infringement of, or induce infringement of any valid and enforceable claim of U.S. Patent No. 5,569,652.

9. Sandoz is entitled to a judgment that Sandoz's manufacture, import, use, sale (and/or offer to sell) of drospirenone (=dihydrospirorenone) and ethinylestradiol drug products does not infringe, contribute to, or induce infringement of any valid and enforceable claim of U.S. Patent No. 5,569,652.

**Second Counterclaim**

**DECLARATORY JUDGMENT OF INVALIDITY  
OF U.S. PATENT 5,569,652**

10. Sandoz repeats and re-alleges the allegations contained in paragraphs 1 through 9, inclusive, of these Counterclaims as if fully set forth herein.

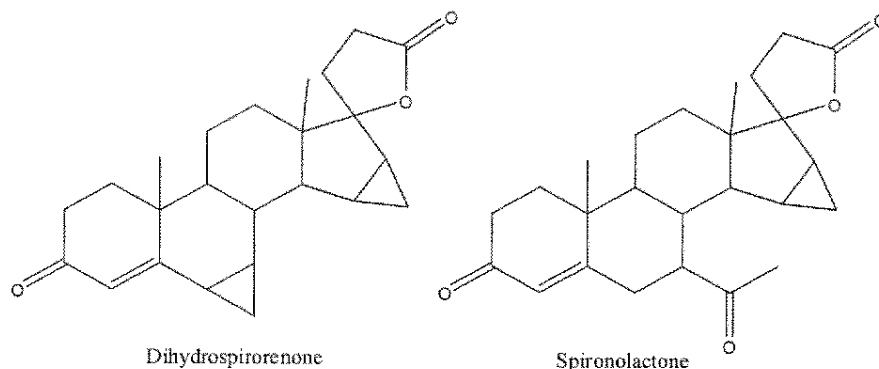
11. The claims of U.S. Patent No. 5,569,652 are invalid for failure to satisfy the provisions of one or more sections of 35 U.S.C. §101 et seq., including without limitation §§ 102, 103, 112 or 282, and/or for double patenting.

12. In particular, dihydrospirorenone was already administered to animals before the earliest priority date of U.S. Patent No. 5,569,652 in dosages that would read on 0.5 to 50 mg (stated in the patent specification at col. 2, lines 4-6, as effective for all uses of the invention) for 70 kg person. As the claims are not limited to human patients, the effect asserted in the claims would therefore have been inherent in such preparations given to animal patients. The claims are therefore invalid via anticipation by inherency.

13. As admitted in the prosecution history of the patent dihydrospirorenone had been disclosed before the earliest priority date of the patent as having anti-aldosterone, gestagen and anti-androgenic properties.

14. It was also known by those of ordinary skill in the art that its close analog, spironolactone was useful clinically in the treatment of hirsutism when used alone (see, e.g., Cumming *et al.*, Treatment of hirsutism with spironolactone. J. Am. Med. Assoc. 247, 1295 – 1298 (March 5, 1982), and increasingly more effective when combined with a contraceptive containing an estrogenic compound (see, e.g., Chapman et al., Spironolactone in combination

with an oral contraceptive: an alternative treatment for hirsutism. *Brit. J. Obstetrics & Gynaecology* 82: 983 – 985 (1985)).



15. Therefore, one of ordinary skill in the art with common sense would have found obvious to screen dihydrospirorenone for clinical usefulness in terms of anti-androgenic activity, alone and in combination with an estrogen, with a reasonable expectation of clinical usefulness.

16. Sandoz is entitled to a judgment that each and every claim of U.S. Patent No. 5,569,652 is invalid.

### Third Counterclaim

#### **DECLARATORY JUDGMENT OF UNENFORCEABILITY OF U.S. PATENT 5,569,652: UNCLEAN HANDS, INEQUITABLE CONDUCT AND PATENT MISUSE**

17. Sandoz repeats and re-alleges the allegations contained in paragraphs 1 through 16, inclusive, of these Counterclaims as if fully set forth herein.

18. The claims of U.S. Patent No. 5,569,652 is unenforceable for acts of inequitable conduct and unclean hands committed during the procurement thereof.

19. On information and belief, Sandoz asserts that Counterclaim-defendants failed to provide the most relevant art to the Examiner in the prosecution of the application leading to U.S. Patent No. 5,569,652, and mischaracterized the data in a reference in order to mislead the Examiner into allowance of the claims of the application ultimately issuing as U.S. Patent No. 5,569,652.

20. Defendant Sandoz alleges that a person of ordinary skill in the art at the time of the invention would understand that the prior art was replete with references to the clinical use of spironolactone, a close analog of dihydrospirorenone, in the treatment of hirsutism, a commonly noted problem in women of advanced age (as noted at col. 1, line 66 – col. 2, line 3 of the specification of U.S. Patent No. 5,569,652), and associated with increased androgen activity. A person of ordinary skill in the art would also understand that spironolactone in combination with oral contraceptives elicited a clinically-enhanced anti-androgenic effect (See, e.g., Chapman et al., Spironolactone in combination with oral contraceptive: an alternative treatment for hirsutism,” *Brit. J. Obstetrics & Gynaecology*, Vol. 92, 983-985 (Sept. 1985)).

21. The failure of Counterclaim-defendants to provide known relevant prior art in the prosecution of the application leading to the patent was material, and the circumstantial factors surrounding such failure support an intent to deceive, thereby evidencing inequitable conduct in the procurement of U.S. Patent No. 5,569,652 and procurement of the patent by unclean hands. Because of inequitable conduct and procurement of the patent by unclean hands, U.S. Patent No. 5,569,652 is unenforceable.

22. U.S. Patent No. 5,569,652 discloses a known compound, dihydrospirorenone (DHSP, also known as drospirenone), preferably together with an estrogen,

that can be used as a pharmaceutical agent for the treatment of androgen-dependent disorders, as well as providing for contraception (column 1, lines 24-32). Therein patentees state:

“It has now been found that the compound of formula I [dihydrospirorenone], *in addition to its gestagen and antialdosterone effect, surprisingly exhibits a strong antiandrogenic activity component*, and specifically at doses that also make possible the formulation of this compound as an oral contraceptive” (*Emphasis added*)

23. During the prosecution of the application of U.S. Patent No. 5,569,652, Bayer Schering acknowledged that the prior art, as in DE-A-26 52 761, disclosed that dihydrospirorenone is an antimineralcorticoid of the aldosterone-antagonist type. Bayer Schering further admitted that prior art, as in DE-A 30 22 337, showed that dihydrospirorenone exhibits a marked gestagen effect, and can be used alone or in combination with estrogens in contraceptive preparations (U.S. Patent No. 5,569,652 column 1, lines 24-32). Thus, the antialdosterone and gestagen properties of dihydrospirorenone were admitted to be prior art to the filing of the application maturing to U.S. Patent 5,569,652. As such, the anti-androgenic properties of dihydrospirorenone, if established, would have been a key factor during prosecution, leading to an assignment of novelty.

24. In the prosecution history of U.S. Patent No. 5,569,652, while Counterclaim-defendants argued for two office actions that the references of art raised by the Examiner did not teach an anti-androgenic effect associated with dihydrospirorenone (see “Amendment” dated June 4, 1991, page 3), the Counterclaim-defendants ultimately acknowledged, after the filing of a continuation application and an information disclosure statement, that the prior art did indeed teach the anti-androgenic effect of dihydrospirorenone (see Preliminary Amendment, filed February 14, 1992, stamped received May 6, 1992). Bayer Schering disclosed three prior art references: Breiner *et al.*, “Inhibition of Androgen Receptor

Binding by Natural and Synthetic Steroids in Cultured Human Genital Skin Fibroblasts,” *Klin. Wochenschr.*, 64:732-737 (1986); Nishino *et al.*, *Acta Endocrinologica*, Supplement 246, Vol. 99 (1982), p. 93, Abstract 105; and Nishino *et al.* *Arch. Pharmacol.*, Vol. 316 (1981), R49.

With respect to the three references, Counterclaim-defendants’ representative states:

“ While the above references taken in combination do indicate antiandrogenic activity for dihydrospirorenone, they do not disclose that dihydrospirorenone will function as a strong antiandrogenic agent or that its level of antiandrogenic [action] makes it possible for use in an oral contraceptive” *Id.* at page 4.

25. Counterclaim-defendants, however did not disclose to the Examiner, as would be known by one of ordinary skill in the art, that spironolactone, a close analog of dihydrospirorenone, was already known as a relatively strong anti-androgenic compound in clinical use (See, e.g. Cumming *et al.* *Treatment of hirsutism with spironolactone*, *JAMA* vol. 247, 1295- 1298 (March 5, 1982), and that its anti-androgenic activity was significantly improved when administered along with a contraceptive containing an estrogen (see, e.g., Chapman *et al.*, *Spironolactone in combination with an oral contraceptive: an alternative treatment for hirsutism. Brit. J. Obstetrics & Gynaecology* 82: 983 – 985 (1985)). Such failure to disclose hid the obvious suggestion that dihydrospirorenone, as a close analog of spironolactone, would also have anti-androgenic action that would be strong, and could be used in an oral contraceptive.

26. Counterclaim-defendants further when filing an Information Disclosure Statement disclosing prior art references that taught the anti-androgenic effect of dihydrospirorenone, further mischaracterized at least one reference that disclosed test results on the relative binding activity of compositions, including dihydrospirorenone and spironolactone, with respect to the dihydrotestosterone receptor in human genital skin fibroblasts, that is, Breiner

*et al.*, Inhibition of Androgen Receptor Binding by Natural and Synthetic Steroids in Cultured Human Genital Skin Fibroblasts, *Klin. Wochenschr.*, 64:732 -737 (1986) by stating to the Examiner that such reference showed that for dihydrospirorenone “the binding affinity for the androgen receptor is low in comparison to the most potent competitors tested” and that the data does not suggest that “dihydrospirorenone will function as a strong antiandrogenic agent or that its level of antiandrogenic makes it possible for use in an oral contraceptive.” April 3, 1992, Preliminary Amendment, page 3.

27. In fibroblast culture, in a physiologically relevant assay, the Breiner reference teaches the relative binding affinity of natural and synthetic steroids toward human androgen receptors in genital skin, an androgen target organ. In Table 1, the reference compares the relative binding affinities (RBA) of spironolactone and dihydrospirorenone toward the androgen receptor. As evidenced in column four of Table 1, in an direct head-to-head comparison, the RBA’s of spironolactone and dihydrospirorenone are 0.8 and 0.3 respectively. Due to the nature of the variability in the art, an artist of ordinary skill would immediately recognize that these assay results are effectively equal within experimental error, and that spironolactone and dihydrospirorenone show very similar if not equal binding activities toward the human androgen receptor. Thus, the Breiner reference teaches that spironolactone and dihydrospirorenone are roughly equal in binding activity.

28. One mechanism whereby a compound exerts anti-androgenic activity is to directly bind an androgen receptor and prevent the binding of an endogenous androgen agonist. *A priori*, such a binding test cannot predict agonist or antagonist activity as indicated by Counterclaim-defendants in their April 3, 1992 Preliminary Amendment (“the model employing fibroblast cultures” in Breiner et al. “does not determine whether a competitor for the receptor

will function as an agonist or antagonist *in vivo*.” However, highly similar compounds such as spironolactone and dihydrospirorenone would be expected to behave similarly based on such a test. Breiner *et al.* state in the Summary that “...this receptor assay in combination with pharmacokinetic and metabolic studies appears to be a useful screening test for androgen and antiandrogen therapy”. Based on the stated utility of the test, the roughly equal activities of spironolactone and dihydrospirorenone, the knowledge that spironolactone was an anti-androgen clinically useful in Hirsutism (as in U.S. Patent No. 4,347,245), and the similarity of their structures, one of ordinary skill would reasonably expect that dihydrospirorenone would possess the qualities of a strong anti-androgen. This assertion is buttressed, at the bottom of page 736, first column, where Breiner *et al.* state: “...we confirmed that spironolactone, an aldosterone antagonist which can exert antiandrogenic effects, does indeed compete for the androgen receptor”. Thus, by simple analogy, dihydrospirorenone would be expected to compete for the androgen receptor and exert anti-androgenic effects similar to spironolactone.

29. In statements of material fact to the Examiner, Counterclaim-defendants, who were fully knowledgeable of the Breiner reference at the time, committed inequitable conduct by misrepresenting the content and teachings of this material reference. Applicants stated, referring in part to the Breiner reference, and that the references cited in combination “do not disclose that dihydrospirorenone will function as a strong anti-androgenic agent, a statement that is factually untrue, *inter alia* because of the teaching found in the Breiner reference in Table 1. Because Counterclaim-defendants were fully aware of the content and teachings of the Breiner reference, Counterclaim-defendants made the statement with intent to deceive the U.S. Patent and Trademark Office.

30. Bayer Schering's mischaracterization of the prior art was material, and the circumstantial factors surrounding such failure and mischaracterization support an intent to deceive, thereby evidencing inequitable conduct in the procurement of the U.S. Patent No. 5,569,652, and procurement of the patent by unclean hands. Because of inequitable conduct and procurement of the patent by unclean hands, U.S. Patent No. 5,569,652 is unenforceable.

31. As set forth above in respect of obviousness, a person of ordinary skill in the art using common sense, knowing that dihydrospirorenone had already been shown to have gestagenic, anti-aldosterone and anti-androgenic activity, and knowing the clinical effectiveness of spironolactone, a close structural analog of dihydrospirorenone, in the treatment of androgenic symptoms in females when used alone and in particular its enhanced anti-androgenic effect when administered along with an estrogenic compound, would have found obvious to try dihydrospirorenone as a clinically effective anti-androgenic agent, whether alone or in combination with estrogen, with a reasonable expectation that it would show an strong anti-androgenic effect such as seen with spironolactone. Under the Supreme Court decision in *KSR International Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 82 U.S.P.Q.2d 1385 (2007), as well as the Federal Circuit decision in *Pfizer v. Apotex*, 480 F.3d 1348 (Fed. Cir. 2007), both of which issued before the filing of the complaint by Counterclaim-defendants, it is clear that mere routine testing of a product with a reasonable expectation of success does not raise to non-obviousness. As the claims of such patent are clearly invalid as obvious, any assertion of the patent after these cases is clearly unwarranted and constitutes patent misuse and litigation misconduct. Similarly, knowing that the patent claims are not limited to a use in humans, and knowing that the dosages of dihydrospirorenone indicated in the specification to be useful for all uses of the invention were administered to female animals prior to the earliest priority date of the patent, by asserting

such patent, Counterclaim-defendants are participating in patent misuse and litigation misconduct.

#### **Fourth Counterclaim**

##### **VIOLATIONS OF THE SHERMAN ACT**

32. Sandoz repeats and realleges paragraphs 1-31, inclusive, of these Counterclaims as if fully set forth herein.

##### **FDA Regimen Regulating New Drugs and Generics**

33. Under the Federal Food, Drug, and Cosmetic Act (“FD&C Act”) (21 U.S.C. §§ 301 et seq.), approval by the Federal Food & Drug Administration (“FDA”) is required before a pharmaceutical company may introduce or deliver a new drug for introduction into interstate commerce. Premarket approval for a new drug, often referred to as an “innovator drug” or “branded drug,” is obtained by filing a New Drug Application (“NDA”) with the FDA demonstrating that the new drug is safe and effective for its intended use.

34. New drugs that are approved for sale in the United States by the FDA almost invariably are covered by patents. The approved NDA holder has the exclusive right under its patent rights to sell its branded drug in the United States for the duration of the patents covering the branded drug, plus any extension of the original patent period (“FDA Exclusivity Period”) granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 (“Hatch-Waxman Act”). Market exclusivity, as for example granted for introducing a new molecular entity, and Pediatric exclusivity that can be added to market and/or patent exclusivity, may also prevent sales of competing products.

35. Once the safety and effectiveness of a new drug is approved by the FDA based on the safety and efficacy data contained in its NDA, the approved new drug may only be used in the United States under the direction and care of a licensed medical practitioner who writes a prescription for his or her patient specifying the drug by name which the patient must then purchase from a licensed pharmacist or other approved provider. The pharmacist must, in turn, fill the prescription with the drug brand specified by the physician unless a generic version of that branded drug has been approved.

36. The holder of the NDA for each new drug approved by the FDA is responsible for listing each patent that it owns that covers its approved branded drug, except for patents covering processes for making only, in the FDA's publication "Approved Drug Substances With Therapeutic Equivalents Evaluations" (the "Orange Book"). The FDA's Role in listing patents in the Orange Book is merely the ministerial task of recording the patents listed by the NDA holder. The FDA does not review the patents listed to determine whether or not, in fact those patents cover the drug in question.

37. Generic drugs are products which the FDA has found to be bioequivalent to approved branded drugs, providing the same therapeutic benefits as the approved, branded drugs. Since generic drugs are invariably priced lower than the original approved branded product, the approved branded drug ordinarily loses a major portion of its sales to generic competitors within a relatively short span after the expiry of any patent and market exclusivity periods. The beneficiaries of this price competition are, of course, American consumers who are able to buy the drugs they need at the lower prices competition induces.

38. If a generic exists and the prescriber does not specify the brand name product without substitution pursuant to state law, the pharmacist may fill the prescription by substituting a generic equivalent that has been shown to have the same therapeutic benefits as the innovator drug. Moreover, many health insurance companies encourage patients to use generic drugs by, among other things, providing for high co-pays on brand name products having generic equivalents or reimbursing patients who choose generics with a greater portion of their out-of-pocket costs. Hospitals, government agencies, and managed health-care entities also generally prefer to purchase generic over pioneer drugs because of the cost-savings involved.

39. The Hatch-Waxman Act provides that a party seeking expedited FDA approval of a generic pharmaceutical may file an Abbreviated New Drug Application (“ANDA”) relying on the safety and efficacy data filed by the NDA holder covering the innovator drug. If the generic manufacturer can show the bioequivalence of the generic to the innovator, the ANDA may be approved by the FDA.

40. While the approval process for generics is streamlined to a degree by the use of ANDAs, it still remains lengthy, costly, and complex due to the inherent difficulties in proving that a generic is, indeed, bioequivalent to the branded drug.

41. The branded drug owner, upon receiving such a Paragraph IV Certification, then has 45 days to initiate a patent infringement suit against the ANDA applicant or if no action is initiated within 45 days of the Paragraph IV certification, FDA approval of the generic product proceeds without regard to patent issues (although the name brand company may sue for patent infringement once a generic product is placed into the marketplace). However, in the event that a patent infringement suit is brought by the NDA holder within the 45-day

window, then FDA approval is automatically stayed until either the earlier of the patents at issue expire or are found by a court to be invalid, non-infringed, or unenforceable, or 30 months from the patentee's receipt of notice of a Paragraph IV filing by the generic company passes.

42. The FD&C Act provides that the first applicant submitting an ANDA with a Paragraph IV Certification ("First Filer") is entitled to an 180-day exclusivity period before other ANDAs for the same generic product can be approved by the FDA. The objective of this period of market exclusivity with respect to any other generic company seeking to produce a competitive product pursuant to an ANDA filing is to provide generic drug producers with an incentive to challenge the validity or applicability of the patents covering a pioneer drug in court.

43. Generally, to obtain pricing as a generic product, the generic company must maintain a price at least 10% below the proprietary brand name price. During the 180-day market exclusivity period, and/or during any period of time in which the First Filer recognizes that no other generic is capable of entering the marketplace (due either to a lack of other generic ANDA filers or the other ANDA filers are, owing to a 30 month stay, unable to obtain ANDA final approval from the FDA), it is not uncommon for the First Filer to maintain approximately a 10% discount on the brand name price. Upon entry of a second generic product into the marketplace, the First Filer not uncommonly finds its price eroded on the order of 30 – 50%. Prices often further plummet after the entrance of a third or fourth generic product. Thus, the number of generic entrants into the marketplace has a significant effect on the ultimate price to the consumer, the speed of erosion of brand name product sales, and the sales revenue that ultimately will be realized by the first generic entrant into the marketplace.

**Violations and Injury to Sandoz and Harm to Public**

**Intentional Mislisting of a Patent in the Orange Book to Maintain a Monopoly**

44. Counterclaim-defendants are the holders of NDA No. 021098 which provides for the use of Yasmin<sup>®</sup> 28 tablets (drospirenone (= dihydrospirorenone) 3 mg and ethinylestradiol 0.03 mg) for oral contraception.

45. Pursuant to 505(b) of the FD&C Act, 37 C.F.R. §314.53 requires that a holder of an NDA submit information regarding each patent that claims the approved drug which is the subject of the NDA or a method of using that drug that “could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product.” As a Paragraph IV certification against any listed patent causes the FDA to stay final approval of an ANDA for 30 months, an applicant is permitted ONLY to “submit information ... on those patents that claim the drug substance that is the subject of the pending or approved application or that claim a drug substance that is the same as the active ingredient that is the subject of the approved or pending application.” *Id.* Specifically, for method of use patents, the applicant “shall submit information only on those patents that claim indications or other conditions of use that are described in the pending or approved method of use and related patent claim.” *Id.* For approved applications, “the applicant submitting the method-of-use patent shall identify with specificity the section of the approved labeling that corresponds to the method of use claimed by the patent submitted.” *Id.*

46. U.S. Patent No. 5,569,652 is the only patent asserted against defendant Sandoz. By filing suit under this patent, Counterclaim-defendants obtained a 30-month stay

from the FDA's grant of final approval of defendant's ANDA. Without such suit, approval of defendant's ANDA would have been greatly expedited.

47. Counterclaim-defendants submitted for listing in the Orange Book U.S. Patent Nos. 5,569,652, 6,787,531, and 6,933,395 as having claims covering the product Yasmin<sup>®</sup>. U.S. Patent No. 5,569,652 contains claims directed only to methods of use. The method of use claimed in U.S. Patent No. 5,569,652 does not correspond to any method of use found in the approved labeling for Yasmin<sup>®</sup>. U.S. Patent No. 5,569,652 is listed in the Orange Book with the Use Code U-1 which states "Prevention of Pregnancy." However, Counterclaim-defendants were well aware that the '652 Patent does not contain claims that in fact cover "Prevention of Pregnancy" as a use in itself or that cover an approved use of Yasmin<sup>®</sup>. Rather the claims cover the intentional treatment of a unique patient population that may be advantaged not only by the uterine effect associated with contraceptives but also an anti-androgenic effect and an anti-aldosterone effect.

48. The listing of U.S. Patent No. 5,569,652 in the Orange Book needed to be accompanied by an attestation that such patent covers the approved uses of Yasmin<sup>®</sup>, which was made by Counterclaim-defendants. The effect of the listing of U.S. Patent No. 5,569,652 in the Orange Book was to cause the FDA to require every filer of an ANDA for a generic version of Yasmin<sup>®</sup> to also submit a Notice of Certification to Counterclaim-defendants on the patent.

49. At the time of the listing, and at the time of commencement of this suit, Counterclaim-defendants were aware that none of the claims of U.S. Patent No. 5,569,652 covered any approved method of use associated with Yasmin<sup>®</sup>, and that there was no provision in the labeling of Yasmin<sup>®</sup> that was specifically directed towards such method of use.

50. At the time of this suit, Counterclaim-defendants understood that irrespective of the intentional mis-listing of U.S. Patent No. 5,569,652 in the Orange Book, that it would obtain a 30-month stay against FDA approval of Defendant's ANDA if it filed suit within 45 days of the date of receipt of the notification of a Paragraph IV certification.

51. As a direct consequence of the violations alleged herein and as planned and calculated by Counterclaim-defendants, Sandoz has been severely injured in its business and property in that it has incurred expenses it would not have incurred in the absence of Counterclaim-defendants' conduct as aforesaid; and Sandoz' business and property have been damaged and impaired. Sandoz has also lost profits that it would have made if it was allowed to enter the generic Yasmin<sup>®</sup> market earlier, allowing it to obtain a substantially larger penetration into the stock of pharmacies and wholesalers. Sandoz will continue to sustain damages indefinitely as a direct and proximate result of Counterclaim-defendants' acts. At this time, the precise amount of Sandoz' damages cannot currently be ascertained but, clearly, if Counterclaim-defendants' conduct continues will reach into the hundreds of millions of dollars.

Intentional Assertion of a Patent Known to Have Been Obtained by Inequitable Conduct

52. As set forth above, Counterclaim-defendants obtained U.S. Patent No. 5,569,652 by affirmative misrepresentation of material facts, failing to disclose highly relevant material information, and submitting false material information, all with an intent to deceive. Counterclaim-defendants knew or should have known of the materiality of its misrepresentations and false representations and of the material it withheld.

53. Counterclaim-defendants knowingly and intentionally failed to provide the prior art, and made material misrepresentations to the office, as set forth above.

54. This litigation is brought in bad faith, in that among other matters discussed herein, Counterclaim-defendants are knowingly and intentionally asserting a patent known to them to have been obtained inequitably, and to be irrelevant in respect to the requirements for an Orange Book Listing, providing Counterclaim-defendants with a 30-month stay of Sandoz's final approval of its ANDA by the FDA. By such bad faith commencement of this action, Sandoz had suffered injury by being prevented from its lawful right to sell a competing generic Yasmin product in the United States, injury that flows directly from the conduct that makes Counterclaim-defendants' acts unlawful.

Misuse of U.S. Patent No. 5,569,652 to Obtain or Coerce an Unfair Advantage

55. Counterclaim-defendants have asserted rights under its patent in a manner designed to obtain and coerce an unfair advantage. By listing its patent in the Orange Book with full knowledge that such patent should not be listed, Counterclaim-defendants have engaged in an activity that has impermissibly broadened the scope of its patent grant with anticompetitive impact.

56. Furthermore, as Counterclaim-defendants knew of prior art invalidating the claims it was seeking in the prosecution of the application leading to U.S. Patent No. 5,569,652, and which it knew at the time of filing of this suit make such patent claims invalid, the improper and bad faith attempt to enforce the patent constitutes patent misuse.

57. Counterclaim-defendants also knew at the time of the filing of this suit, that claims encompassing subject matter that was clearly obvious-to-try under *KSR v. Teleflex*, 550 U.S. \_\_\_, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007), with a reasonable expectation of success, are not patentable.

58. As Counterclaim-defendants understood that the prior art discussed above made the subject matter asserted in all of its claims of U.S. Patent No. 5,569,652, obvious-to-try with a reasonable expectation of success, Counterclaim-defendants understood that U.S. Patent No. 5,569,652 was invalid in its entirety for obviousness, and that any action brought under the patent would be objectively baseless and subjectively meritless, and would cause antitrust injury to its competition.

#### Sham Litigation

59. With respect to the patent-in-suit, Counterclaim-defendants knew that this action is baseless. Nevertheless, Counterclaim-defendants commenced this action in bad faith for the improper purpose of imposing collateral, anticompetitive injury to Sandoz by precluding and delaying Sandoz and all other competitors from entering the drospirenone (= dihydrospirorenone)/ethinylestradiol market, thereby monopolizing or attempting to monopolize the market and/or further perpetuating its monopoly power in the sale and distribution in the United States of drospirenone (= dihydrospirorenone)/ethinylestradiol and the oral contraceptive marketplace in the United States in general, and preventing Sandoz from earning profits from sales of this pharmaceutical product.

60. Upon information and belief, Counterclaim-defendants have a policy and practice of starting and maintaining legal proceedings against Sandoz and others, for the sole purpose of obtaining automatic stays of final FDA approval without regard to the merits of those actions.

61. Sandoz devoted a significant amount of time, effort and resources (monetary and otherwise) to the development, preparation and filing of its ANDA No. 90-114 and in the development of its product and manufacturing lines.

62. The knowing and willful acts of Counterclaim-defendants in seeking to baselessly enforce U.S. Patent No. 5,569,652 against Sandoz constitute a sham litigation by reason of which Sandoz has been and will continue to be injured in its business and property and has suffered and will continue to suffer damages.

63. This litigation is objectively and subjectively sham litigation that falls within the sham exception to the *Noerr-Pennington* doctrine. The lawsuit is objectively baseless in that no reasonable litigant could realistically expect success on the merits given the mislisting of the patent, the obviousness of the subject matter claimed therein, and the intentional misrepresentations and the withholding of highly material information from the USPTO in obtaining the patent.

64. Sandoz is entitled to recover threefold the damages it has sustained, the costs of suit, and reasonable attorneys' fees and, under 15 U.S.C. § 26, Sandoz is entitled to injunctive relief, including dismissal of the present action and an order restraining Counterclaim-defendants from any further or future enforcement of U.S. Patent No. 5,569,652 against Sandoz.

#### Conspiracy In Restraint of Trade

65. On June 24, 2008, Counterclaim-defendants reported to the public that they had entered into a settlement agreement on Yasmin<sup>®</sup> with Barr Pharmaceuticals, Inc., ("Barr") a company which had filed an ANDA to produce a generic version of Yasmin<sup>®</sup> earlier

than Sandoz. Counterclaim-defendants had sued Barr in the District Court of New Jersey on a different patent listed in the Orange Book, U.S. Patent No. 6,787,531 (the '531 patent) owned by Counterclaim-defendants. Under the terms of settlement agreement as publicly reported, Counterclaim-defendants have allowed Barr to market and distribute, on a sole and exclusive basis, a generic version of Yasmin<sup>®</sup> in the United States as of July 1, 2008.

66. Irrespective of whether Barr ultimately prevailed on its claim of invalidity of U.S. Patent No. 6,787,531, and irrespective of the fact that Counterclaim-defendants did not assert U.S. Patent No. 5,569,652 during the 45-day period after receiving Barr's certification notice of non-infringement and/or invalidity with respect to U.S. Patent No. 5,569,652, Counterclaim-defendants could have asserted U.S. Patent No. 5,569,652 against Barr should it have decided to enter the marketplace with a generic Yasmin<sup>®</sup> upon final approval of its ANDA by the FDA, seeking injunctive relief and damages under the patent.

67. Instead of asserting U.S. Patent No. 5,569,652 against Barr in the future, which by bringing this suit against Sandoz Counterclaim-defendants have implicitly asserted is valid and enforceable, on information and belief Counterclaim-defendants chose to enter into an anticompetitive agreement, both implicit and explicit, with Barr under which Counterclaim-defendants agreed to enforce U.S. Patent No. 5,569,652 and/or one or more of its other Orange Book listed patents for the product Yasmin<sup>®</sup> against any subsequent generic competitor in order to prohibit entry of such generic competitor by obtaining an undeserved 30-month stay against FDA approval of such subsequent generic competitor's ANDA. On information and belief, Barr and Counterclaim-defendants entered into such agreement in order to fix prices for drospirenone (=dihydrospirorenone)/ethinylestradiol at a high level while restraining trade or commerce in the generic Yasmin<sup>®</sup> market by suppressing competition. On information and belief, Barr and

Counterclaim-defendants had a meeting of the minds in respect of such unlawful arrangement, and a unity of purpose, design and understanding to engage in such unlawful conspiracy.

68. On information and belief, the explicit settlement agreement provides that Counterclaim-defendants will remain the sole supplier of product to Barr and Barr will pay a substantial portion of its revenues on any generic Yasmin<sup>®</sup> sales as long as Barr is the sole purveyor of generic Yasmin.<sup>®</sup> The percentage of revenue payable to Counterclaim-defendants increases significantly if Counterclaim-defendants prevails on appeal in demonstrating to the Federal Circuit the validity of the '531 patent. On information and belief, under the terms of the settlement agreement, whether or not Counterclaim-defendants prevail on their appeal, Counterclaim-defendants will maintain a substantial portion of their overall share of the oral contraceptive marketplace on a dollar volume basis while Barr is the sole purveyor of its generic Yasmin.<sup>®</sup> This share will be maintained by Counterclaim-defendants while Counterclaim-defendants will not have to incur any costs related to restructuring of its Yasmin<sup>®</sup> manufacturing infrastructure, as would have occurred if Counterclaim-defendants were not producing the product for Barr. Such settlement agreement acts as a subterfuge for Counterclaim-defendants' maintaining their market power.

69. On information and belief, among the agreements made by the parties to the settlement is one which Counterclaim-defendants require upon notice by Barr of a potential third-party infringer of one or more Counterclaim-defendants' patents covering Yasmin<sup>®</sup>, to enforce their patents covering Yasmin<sup>®</sup> against such third party. Such provision effectively prevents any third party ANDA filer from selling generic Yasmin<sup>®</sup> for 30 months of its ANDA filing date provided Counterclaim-defendants bring suit within 45 days of receiving the third-party's notice letter. Patents held by Counterclaim-defendants which are said to cover Yasmin<sup>®</sup>

include non-process manufacturing patents, such as U.S. Patent No. 5,569,652 which is asserted against Sandoz, that a person of ordinary skill in the art would understand to be invalid or unenforceable.

70. Impartial observers would have expected U.S. Patent No. 5,569,652 to be cited against Barr to enjoin it from continuing sales of a generic Yasmin<sup>®</sup> product if the decision of the District Court of New Jersey finding invalidity of the '531 for obviousness was upheld at the Court of Appeals for the Federal Circuit were the '531 patent considered by Counterclaim-defendants to be valid and enforceable.

71. On information and belief, the agreement between Counterclaim-defendants and Barr was entered into by Counterclaim-defendants with the specific intent to maintain Counterclaim-defendants' monopoly power in the drospirenone (=dihydrospirorenone)/ethinylestradiol market and to attempt to monopolize the U.S. oral contraceptive marketplace overall. On information and belief, such agreement was entered into by Counterclaim-defendants and Barr to allow for artificially high prices to be set in the drospirenone (=dihydrospirorenone)/ethinylestradiol market while retraining any further generic competition so as to allow both Counterclaim-defendants and Barr to share in monopoly profits.

72. The agreement between Counterclaim-defendants and Barr was structured to provide for unfair anticompetitive conduct to use known invalid or unenforceable patents to keep any third party without supply and price ties to Counterclaim-defendants from entering into the drospirenone (=dihydrospirorenone)/ethinylestradiol market, and to keep further generic entrants from generally competing within the broader oral contraceptive marketplace. There is

the dangerous probability that Counterclaim-defendants will unlawfully monopolize the market for oral contraceptives if such unfair anticompetitive conduct is not prohibited.

**Antitrust Activity in the Relevant Market**

73. Yasmin<sup>®</sup> is marketed as having unique antimineralocorticoid (antialdosterone) and anti-androgenic properties, allowing for exceptional control of acne and a reduction in fluid retention-related symptoms. In particular, Yasmin<sup>®</sup>'s success in the marketplace is based on studies that show it causes significantly less fluid retention when compared to other oral contraceptive pills, while providing similar contraceptive ability. Fluid retention is one of the primary reasons for women to discontinue the use of oral contraceptives. Many women suffer significantly from the fluid retention associated with other oral contraceptives. There are no products that are reasonably interchangeable by consumer. The relevant market therefore is the drospirenone (=dihydrospirorenone)/ethinylestradiol market given the unique properties of this contraceptive combination.

74. On information and belief, sales of products sold by Counterclaim-defendants constitute approximately half of the entire oral contraceptive market in the United States. On information and belief, because of its large market share, Counterclaim-defendants have and have had the power to control prices in the oral contraceptive marketplace. The oral contraceptive marketplace accounts for a substantial portion of Counterclaim-defendants' healthcare sales.

75. Counterclaim-defendants have knowingly and willfully relied upon the '652 Patent to obtain a 30-month automatic stay of FDA final approval of Sandoz's ANDA. The purpose and effect of Counterclaim-defendants' actions was to block defendant Sandoz from

entering the market for drospirenone (=dihydrospirorenone)/ethinylestradiol, a market in which Counterclaim-defendants have monopoly power (controlling 100 percent of the sales of such product in the United States). As a result of such conduct, consumers have been deprived of the benefits of lower-priced generic competition for Yasmin<sup>®</sup> that might have occurred had the FDA granted final approval to Sandoz's ANDA before 30 months from the date of filing of this suit. The prices for Yasmin<sup>®</sup> products continue at artificially high and monopolistic levels as a result of Counterclaim-defendants' illicit and anticompetitive acts.

76. As indicated above, Counterclaim-defendants currently possess monopoly power in the drospirenone and ethinylestradiol drug product market in the United States, the relevant geographic market in which to assess the anticompetitive effects of Counterclaim-defendants.

77. Counterclaim-defendants have monopolized, attempted to monopolize, conspired to monopolize and unlawfully restrained trade by engaging in the aforementioned anticompetitive acts and practices, including: (1) wrongly listing U.S. Patent No. 5,569,652 against its Yasmin<sup>®</sup> product in the Orange Book although it knew the claims of such patent did not cover an approved use of Yasmin<sup>®</sup> in order to obtain an automatic 30-month stay against the grant of final approval to a generic equivalent; (2) wrongly listing U.S. Patent No. 5,569,652 in the Orange Book although it knew such patent to have been obtained inequitably; (3) unlawfully instituting and maintaining objectively baseless sham litigation against defendant Sandoz; and (4) entering into a conspiracy with Barr to artificially maintain high prices for drospirenone (=dihydrospirorenone)/ethinylestradiol sold in the United States, while restraining any further competition in such marketplace. Such monopolization has raised substantial barriers to entry into the relevant market and given Counterclaim-defendants the power to exclude competition, thereby depriving consumers of the benefits of lower-priced generic competition. Such acts and

practices are anticompetitive in nature and tendency and constitute an unfair method of competition.

78. Counterclaim-defendants' actions are intended to protect their monopoly position in the sale of drospirenone (= dihydrospirorenone)/ethinylestradiol, constitute an attempt to monopolize oral contraceptive product sales in the United States and have resulted in harm to competition in violation of § 2 of the Sherman Act, 15 U.S.C. § 2.

79. Counterclaim-defendants' actions are intended to protect their market power in the sale of drospirenone (= dihydrospirorenone)/ethinylestradiol and comprise an unlawful contract and conspiracy in restraint of trade in violation of § 1 of the Sherman Act, 15 U.S.C. § 1.

80. Such actions by Counterclaim-defendants have caused and will continue to cause the prices charged to the public for drospirenone (= dihydrospirorenone)/ethinylestradiol to be maintained at anticompetitive levels and have prevented competitors from entering the market to sell drospirenone (= dihydrospirorenone)/ethinylestradiol drug products at prices significantly below those of Counterclaim-defendants or their licensee Barr.

#### **Fifth Counterclaim**

##### **NEW YORK COMMON LAW UNFAIR COMPETITION**

81. Sandoz repeats and re-alleges the allegations contained in paragraphs 1 through 80, inclusive, of these Counterclaims as if fully set forth herein.

82. Counterclaim-defendants' acts and omissions as set forth herein constitute deceptive and unconscionable commercial practices and unlawful practices within the scope of New York's common law unfair competition.

83. Specifically, by asserting a patent which it knows to be invalid and/or unenforceable, and which it has no good faith belief to be infringed, Counterclaim-defendants' representatives have undertaken activities to interfere with defendant Sandoz's present and future business interests regarding the sales of its generic Yasmin<sup>®</sup> product. Counterclaim-defendants have asserted such invalid/unenforceable patents for the purpose of creating litigation costs that are excessive relative to market share.

84. Such deceptive and unconscionable commercial practice activities continue irrespective of its knowledge that U.S. Patent No. 5,569,652 is invalid and/or unenforceable, as set forth herein.

85. As a result of Counterclaim-defendants' unlawful practices in violation of New York unfair competition law, defendant Sandoz has been substantially damaged.

### **Sixth Counterclaim**

#### **TORTIOUS INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE**

86. Sandoz repeats and re-alleges the allegations contained in paragraphs 1 through 85, inclusive, of these Counterclaims as if fully set forth herein.

87. Sandoz has a continuing economic advantageous relationship with others for the supply of its generic products.

88. Counterclaim-defendants have knowingly interfered with this relationship by filing this lawsuit for the purpose of barring Sandoz and others from beginning to supply generic Yasmin<sup>®</sup> by delaying their final ANDA approval by the FDA.

89. By engaging in the actions set forth herein, Counterclaim-defendants have intentionally interfered with Sandoz's present and future business interest with respect to making and selling products containing.

#### **Seventh Counterclaim**

##### **MALICIOUS PROSECUTION**

90. Sandoz repeats and realleges the allegations of paragraphs 1-89 above as if fully set forth herein.

91. Counterclaim-defendants' unlawful acts and conduct as set forth above constitute malicious prosecution.

92. By reason of the foregoing unlawful acts Sandoz has been injured and will continue to be injured in its business and property and has suffered and will continue to suffer damages.

#### **Eighth Counterclaim**

##### **DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF U.S. PATENT NO. 6,787,531**

93. Sandoz repeats and realleges the allegations contained in paragraphs 1 through 92, inclusive, of these Counterclaims as if fully set forth herein.

94. U.S. Patent No. 6,787,531 is also listed in the Orange Book as blocking the marketing of a generic product (patent expiration August 31, 2020). In the case of *Bayer et al. v. Barr Laboratories, Inc.*, Civ. Action No. 05-cv-2308 (D.N.J., Sheridan, U.S.D.J.), the court found all claims of such patent invalid as obvious. Based on the finite number of choices available to improve bioavailability, the court found it obvious to try micronization, and that there was a reasonable expectation of success in doing so.

95. The decision in *Bayer v. Barr* has been appealed to the Federal Circuit. If the decision is overturned, this patent will assuredly be asserted by Counterclaim-defendants in the future to prevent Sandoz's marketing of a generic Yasmin<sup>®</sup> product. Thus under *Medimmune, Inc. v. Genentech, Inc., et al.* 127 S.Ct. 764, 166 L.Ed.2d 604 (2007), Defendant Sandoz is entitled to a declaratory judgment action as the facts alleged, under all the circumstances, demonstrate that there is a substantial controversy between parties having adverse legal interests that are of sufficient immediacy and reality to warrant relief. That is the dispute is concrete touching the legal relations of the parties having adverse legal interest, and is real and substantial, and admits of specific relief through a decree of conclusive character.

96. Sandoz does not infringe, contribute to the infringement of, or induce infringement of any valid and enforceable claim of the '531 patent.

97. Sandoz is entitled to a judgment that Sandoz's manufacture, import, use, sale (and/or offer to sell) of drospirenone and ethinylestradiol drug products does not infringe, contribute to, or induce infringement of any valid and enforceable claim of '531 patent.

**Ninth Counterclaim**

**DECLARATORY JUDGMENT OF INVALIDITY OF ALL OF THE CLAIMS  
OF U.S. PATENT NO. 6,787,531**

98. Sandoz repeats and re-alleges the allegations contained in paragraphs 1 through 97, inclusive, of these Counterclaims as if fully set forth herein.

99. The claims of U.S. Patent No. 6,787,531 are invalid for failure to satisfy the provisions of one or more sections of 35 U.S.C. §101 et seq., including without limitation §§ 102, 103, 112 or 282, and/or for double patenting.

100. Sandoz is entitled to a judgment that each and every claim of U.S. Patent No. 6,787,531 is invalid.

**Tenth Counterclaim**

**DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF  
OF U.S. PATENT NO. 6,933,395**

101. Sandoz repeats and realleges the allegations contained in paragraphs 1 through 100, inclusive, of these Counterclaims as if fully set forth herein.

102. U.S. Patent No. 6,933,395 is also listed in the Orange Book as blocking the marketing of a generic product having a listed patent expiration of August 11, 2017.

103. Even if defendant Sandoz was to prevail on its actions with respect to U.S. Patent Nos. 5,569,652 and 6,787,531, Sandoz would assuredly be faced with a patent infringement suit under U.S. Patent No. 6,933,395 which is also listed as having claims covering the product Yasmin<sup>®</sup>. Thus under *Medimmune, Inc. v. Genentech, Inc., et al.* 127 S.Ct. 764, 166

L.Ed.2d 604 (2007), Defendant Sandoz is entitled to a declaratory judgment action as the facts alleged, under all the circumstances, demonstrate that there is a substantial controversy between parties having adverse legal interests that are of sufficient immediacy and reality to warrant relief. That is the dispute is concrete touching the legal relations of the parties having adverse legal interest, and is real and substantial, and admits of specific relief through a decree of conclusive character.

104. Sandoz does not infringe, contribute to the infringement of, or induce infringement of any valid and enforceable claim of U.S. Patent No. 6,933,395.

105. Sandoz is entitled to a judgment that Sandoz's manufacture, import, use, sale (and/or offer to sell) of drospirenone (=dihydrospirorenone) and ethinylestradiol drug products does not infringe, contribute to, or induce infringement of any valid and enforceable claim of U.S. Patent No. 6,933,395.

#### **Eleventh Counterclaim**

#### **DECLARATORY JUDGMENT OF INVALIDITY OF ALL OF THE CLAIMS OF U.S. PATENT NO. 6,933,395**

106. Sandoz repeats and realleges the allegations contained in paragraphs 1 through 105, inclusive, of these Counterclaims as if fully set forth herein.

107. The claims of U.S. Patent No. 6,933,395 are invalid for failure to satisfy the provisions of one or more sections of 35 U.S.C. §101 et seq., including without limitation §§ 102, 103, 112 or 282, and/or for double patenting.

108. Sandoz is entitled to a judgment that each and every claim of U.S. Patent No. 6,933,395 is invalid.

**Twelfth Counterclaim**

**DECLARATORY JUDGMENT FOR DELISTING OF U.S. PATENT NO. 5,569,652  
FROM THE ORANGE BOOK**

109. Sandoz repeats and re-alleges the allegations contained in paragraphs 1 through 108, inclusive, of these Counterclaims as if fully set forth herein.

110. Section 1101 et seq., and in particular Section 1101(b)(2)(D), of Title XI (“Access to Affordable Pharmaceuticals”) of the Medicare Modernization Act, provides that a defendant in a suit may assert a counterclaim seeking an order requiring the holder of an NDA to delete patent information submitted by the holder to the FDA for listing in the Orange Book on the ground that the patent listed does not claim an approved method of using the drug.

111. As set forth above, the U.S. Patent No. 5,569,562 does not contain claims to an approved method of using the drug. Therefore, such patent should be de-listed, and defendant’s ANDA should no longer be held hostage to an automatic 30 month stay before the FDA can grant final approval to market the drug.

### **PRAYER FOR RELIEF**

WHEREFORE, Defendant-Counterclaimant Sandoz, Inc. ("Sandoz") respectfully prays for the relief requested herein:

1. An Order dismissing Plaintiffs' complaint in its entirety with prejudice;
2. A judgment declaring that Sandoz has not and will not infringe any valid or enforceable claim of U.S. Patent No. 5,569,652, and does not induce or contribute to infringement of any valid and enforceable claim of U.S. Patent No. 5,569,652;
3. That judgment be entered declaring the claims of U.S. Patent No. 5,569,652 invalid and/or unenforceable;
4. A judgment that the claims in the complaint are barred by the statute of limitations, and/or the equitable doctrines of laches, waiver and estoppel and/or the doctrine of unclean hands and/or by reason of actions taken and statements made in the prosecution of the application leading to U.S. Patent No. 5,569,652;
5. An Order enjoining and restraining Plaintiffs, its officers, agents, servants, employees and attorneys and all persons in active concert or participation with it from further charges of infringement or acts of enforcement based on U.S. Patent No. 5,569,652 against Sandoz its actual and prospective customers and suppliers or anyone in privity with Sandoz;
6. A judgment that Plaintiffs violated section 2 of the Sherman Act by asserting U.S. Patent No. 5,569,652 against Sandoz, and awarding to Sandoz three-fold the

damages, including lost profit, costs, expenses, and prejudgment interest, it has incurred plus the costs of suit and its attorneys' fees;

7. A judgment that Plaintiffs violated section 1 of the Sherman Act by entering into agreement with Barr Pharmaceuticals to artificially maintain a high price on drospirenone (= dihydrospirorenone)/ethinylestradiol, and by agreeing under such an agreement that Plaintiffs would assert U.S. Patent No. 5,569,652 against other potential competitors, including Sandoz, and awarding to Sandoz three-fold the damages, including lost profit, costs, expenses, and prejudgment interest, it has incurred plus the costs of suit and its attorneys' fees;

8. A judgment that Plaintiffs, by asserting U.S. Patent No. 5,569,652 against Sandoz, have participated in unfair trade practices in contravention of common law fair trade practices, and awarding to Sandoz damages it has incurred plus the costs of suit and its attorneys' fees;

9. An Order declaring this case "exceptional" pursuant to 35 U.S.C. § 285 and awarding Sandoz its costs and reasonable attorneys' fees;

10. A judgment awarding Sandoz such other and further relief in its favor and against Plaintiffs as the Court deems just and proper.

11. That with respect to the Declaratory Judgment Counterclaim asserted herein, the Court adjudge and decree as follows:

(a) Sandoz has not infringed, does not infringe, and does not induce or contribute to infringement of any valid claim of U.S. Patent Nos. 5,569,652, 6,787,531, and 6,933,395;

(b) That the claims of U.S. Patent Nos. 5,569,652, 6,787,531, and 6,933,395 invalid and/or unenforceable;

(c) That Plaintiffs and their agents, representatives, attorneys and those persons in active concert or participation with them who receive actual notice hereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Sandoz or its actual or prospective customers, dealers or suppliers, clinical investigators, or any prospective or present sellers, dealers, distributors or customers of Sandoz, or anyone in privity with Sandoz, or charging any of them either orally or in writing with infringement of U.S. Patent Nos. 5,569,652, 6,787,531, and 6,933,395;

(d) That an Order be entered declaring this action an exceptional case within the meaning of 35 U.S.C. § 285 and that Sandoz is entitled to recover its reasonable attorneys' fees upon prevailing in this action;

(e) That Sandoz be awarded damages including lost profit, costs, expenses, prejudgment interest and attorneys' fees under 15 U.S.C. § 2 and New York Unfair Competition common law;

(f) That an Order be entered that Plaintiffs account to Sandoz for all gains, profits and advantages realized by Plaintiffs by reason of their acts herein alleged; and

(g) That Sandoz be awarded such other and further relief as the Court deems just and equitable.

Dated: July 11, 2008

KELLEY DRYE & WARREN LLP

s/ Steven J. Moore

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